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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/851,882 | 05/09/2001 | Dipak Ghosh | 210556 | 4321 |

23460 7590 03/17/2003

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EXAMINER

YU, GINA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 03/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,882

Applicant(s)

GHOSH ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Response filed on February 12, 2003. Claims 1-45 are pending. The finality of the office action dated November 12, 2002 is withdrawn in view of applicants' remarks. However, new rejections are made in view of updated search and upon further consideration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley et al. (US 6,468,564 B1) in view of Fänger et al. (U.S. Pat. No. 6,153,204) ("Fänger").

Riley teaches skin care compositions for aging or dry skin. See the serum formulation in Examples 2 and 3. Example 2 contains 0.3 % by weight of diazolidinyl urea and 0.01 % by weight of coenzyme Q10, while Example 3 contains 0.2 % by weight of diazolidinyl urea and 0.01 % by weight of coenzyme Q10. The reference teaches the use of coenzyme Q10 in col. 5, lines 26 – 34, citing its antioxidant and skin protection properties. See the formulation for the additives in instant claims 12-16, 19, 20, and 23-36.

Riley fails to disclose the specific weight ratio of urea and coenzyme Q10 as recited in the instant claims and solid emollients.

Fänger teaches cosmetic or pharmaceutical compositions comprising antioxidants. See col. 4, line 53 – col. 7, line 68. The o/w emulsion in Example 3 comprises 10 wt % urea, and also contains antioxidant and preservatives to a sufficient

quantity. Ubiquinone, vitamin C, tocopherols, and the derivatives thereof are among the conventional antioxidants disclosed in col. 7, lines 13-68. The reference teaches using 0.001-30 wt % of the antioxidants, and in particular 1-10% by weight, which meets the limitation of weight ratio of urea and ubiquinone in instant claims 1, 10, and 11. Also disclosed in Example 3 are preservatives and perfume, which meet instant claims 19 and 32. The amount of water in the example is at most 55.5 %, and the oil phase (PEG-7 hydrogenated castor oil, wool wax alcohol, beeswax, Vaseline, paraffin oil) comprise 26.5 wt % of the composition, meeting instant claims 4, 6, and 20. Also disclosed by the reference are: emulsifier, meeting instant claim 12; thickener, claims 14-16; and anti-inflammatory active ingredients claims 23-24. See col. 6, line 63 – col. 7, line 12. The reference teaches that a mixture of C12-15-alkyl benzoate with oil is advantageously used. See instant claim 21; col. 8, lines 63 – 67. Examiner views that the optimum weight range of the additives not mentioned in this reference would have been discovered by a skilled worker by routine experiments.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Riley by adjusting the amount of coenzyme Q10 as motivated by Fänger because of the expectation of successfully producing a topical composition with an enhanced antioxidant and skin protection property.

Examiner also notes that generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in Riley, examiner views that one having

ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation. Raising the concentration of coenzyme Q10 is viewed obvious because of the expectation of successfully producing a composition with enhanced protection of the skin as taught by the reference.

Given the general teaching of using emollients in Riley, the routineer also would have been motivated to add solid emollients with oils as motivated by Fänger because of the expectation of successfully producing a composition with an enhanced emolliency. The moisturizing property as recited in the instant claim 37 is viewed a result of the obvious variation of the prior arts, absent evidence to the contrary.

2. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley and Fänger as applied to claims 1-42 above, and further in view of Hoppe et al. (U.S. Pat. No. 5,912,272) (Hoppe) in view of Raab (Uses of Urea in Cosmetology, 1990).

Hoppe teaches composition comprising ubiquinones for treating senile xerosis, of which the symptoms include dryness, cracking, roughness skin by providing moisture to the skin. See col. 1, line 9 – col. 2, line 37. The composition preferably comprises 0.2-0.4 by weight of coenzyme Q10. See col. 3, lines 4 – 15. The composition is formulated in W/O or O/W emulsion gel, lotion, or cream. See col. 3, lines 16 – 20; col. 4, lines 53- 60. The additives including emulsifiers, preservatives, buffer substances, thickeners, fragrances, antioxidants, vitamins, and UV protection filters are also to be added in the composition. See col. 3, line 21 – col. 4, line 48. Given the teaching of adding 0.1-10wt % of the UV protection filters to ensure the stability of the oxidation-

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sensitive ubiquinones, examiner views that a skilled worker would have known to optimize the quantity of the components in the composition. The reference lacks the teaching of urea and soothing additives.

Raab teaches the use of urea in concentrations of 4-10 wt % in cosmetic and/or dermatological compositions. See p. 97, col. 2 – p. 98, col. 1. The pharmacological activity of urea, including moisturizing, desquamating antimicrobial, and anti-inflammatory action, are disclosed on p. 98, and its moisturizing effect is discussed throughout the article. The reference teaches urea increases the therapeutic activity of other pharmaceutical substances, and in Table 3 shows the use of urea in combination with anti-inflammatory agents, retinoid or others in the weight ratio of 10: 0.3 to 10: 5, which meets instant claims 23-25. The reference recommends formulating urea-containing compositions in the form of emulsion lotion or cream, meeting instant claims 2, 3, and 38. See p. 102, col. 2. In instant claim 37, examiner views that the limitation on the moisturizing effect of the composition is what is expected of based on the teaching of the combined references.

Given the moisturizing effect of coenzyme Q10 and urea individually, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have expect that the combination of the two component such as the obvious variation of Riley and Fänger, would use the composition for moisturizing effects because of the expectation that the composition would produce an enhanced moisturizing effect.

Response to Arguments

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

Hoppe and Raab respectively teaches that coenzyme Q10 and urea are known to treat dry skin by providing moisturization. Riley and Fänger also teaches that a topical composition comprising urea and coenzyme Q10 within the recited range is an obvious variation of the prior arts. Examiner views that the alleged improvement in moisturizing effect is an expected or obvious result in view of the prior art, absent evidence to the contrary. See MPEP § 716. Evidence supporting unexpected results will be weighted against the prima facie case of obviousness or the closest prior art.

Conclusion

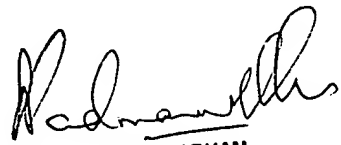
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
March 14, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER 3/14/03